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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/784,232	02/15/2001	Nicholas L. Abbott	032026:0502	2504

7590

10/21/2002

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EXAMINER

TRAN, MY CHAU T

ART UNIT

PAPER NUMBER

1639

DATE MAILED: 10/21/2002

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/784,232

Applicant(s)

ABBOTT ET AL.

Examiner

My-Chau T. Tran

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 July 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-63 is/are pending in the application.
- 4a) Of the above claim(s) 19-63 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☒ The proposed drawing correction filed on 08 July 2002 is: a) ☒ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendment filed 7/8/02 in Paper No. 10 is acknowledged and entered. Claims 1 and 4 are amended. Claim 2 is canceled. Claims 19-63 have been withdrawn from further consideration a being drawn to a non-elected invention. Claims 1 and 3-63 are pending.
2. This application contains claims 19-63 are drawn to an invention nonelected with traverse in Paper No. 7. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Drawings

3. The proposed drawing corrections and/or the proposed substitute sheets of drawings, filed on 7/8/02, have been approved. A proper drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The correction to the drawings will not be held in abeyance.
4. The Patent and Trademark Office no longer makes drawing changes. See 1017 O.G. 4. It is applicant's responsibility to ensure that the drawings are corrected. Corrections must be made in accordance with the instructions below.

INFORMATION ON HOW TO EFFECT DRAWING CHANGES

1. Correction of Informalities -- 37 CFR 1.85

New corrected drawings must be filed with the changes incorporated therein. Identifying indicia, if provided, should include the title of the invention, inventor's name, and

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application number, or docket number (if any) if an application number has not been assigned to the application. If this information is provided, it must be placed on the front of each sheet and centered within the top margin. If corrected drawings are required in a Notice of Allowability (PTOL-37), the new drawings **MUST** be filed within the **THREE MONTH** shortened statutory period set for reply in the "Notice of Allowability." Extensions of time may NOT be obtained under the provisions of 37 CFR 1.136 for filing the corrected drawings after the mailing of a Notice of Allowability. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

2. Corrections other than Informalities Noted by Draftsperson on form PTO-948.

All changes to the drawings, other than informalities noted by the Draftsperson, **MUST** be made in the same manner as above except that, normally, a highlighted (preferably red ink) sketch of the changes to be incorporated into the new drawings **MUST** be approved by the examiner before the application will be allowed. No changes will be permitted to be made, other than correction of informalities, unless the examiner has approved the proposed changes.

Timing of Corrections

Applicant is required to submit acceptable corrected drawings within the time period set in the Office action. See 37 CFR 1.185(a). Failure to take corrective action within the set (or extended) period will result in **ABANDONMENT** of the application.

5. The previous objections and rejections under 35 USC 112, second paragraph, and the judicially created doctrine of obviousness-type double patenting for claims 1-18 have been withdrawn in view of applicant's amendments and arguments. Maintained rejections as set forth in the Office Action of Merit (4/5/02) below along with response to arguments.

Claim Rejections - 35 USC § 102

6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

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7. Claims 1, 3-7, 14 and 16 are rejected under 35 U.S.C. 102(e) as being anticipated by Abbott et al. (US Patent 6,284,197 B1).

Abbott et al. anticipates the claimed invention by teaching a method for detection of an analyte. The method steps include providing a substrate (a first substrate), a binding agent (a recognition moiety), and the detection of the analyte is due to the interaction of the analyte with the binding agent on the substrate. This binding causes a visual distortion of the liquid crystal (mesogens) enabling the detection of the analyte (col. 14, line 16-43). The analyte is a biomolecule (pathogen) (col. 26, line 21-23; col. 29, line 11-15). The detection region (substrate) is coated with gold (gold film) and treated with disulfide (col. 22, line 4-39). The substrate is formed from a polymer, preferably polydimethylsiloxane (col. 15, line 66-67 and continue to col. 16, line 1-14). The binding agent is a peptide, antibody, or protein (col. 26, line 30-36; col. 28, line 53-67). The binding agents are located in the depression of the detection region (col. 40, line 42-44).

8. Claims 1, 3-6, and 14 are rejected under 35 U.S.C. 102(e) as being anticipated by Abbott et al. (US Patent 6,277,489 B1).

Abbott et al. anticipates the claimed invention by teaching a method for detection of an analyte. The method steps include providing a substrate (a first substrate), a binding agent (a recognition moiety), and the detection of the analyte is due to the interaction of the analyte with the binding agent on the substrate. This binding causes a visual distortion of the liquid crystal (mesogens) enabling the detection of the analyte (col. 14, line 16-43). The analyte is a biomolecule (pathogen) (col. 51, line 27-31). The detection region (substrate) is coated with

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gold (gold film) and treated with disulfide (col. 11, line 34-37 and 51-55). The substrate is formed from a polymer (col. 11, line 8-18). The binding agent is a peptide or antibody (col. 19, line 56-59; col. 26, line 18-25).

9. Claims 1, 3-7 and 14 are rejected under 35 U.S.C. 102(f) because the applicant did not invent the claimed subject matter. The inventorship of the US Patent 6,284,197 B1 includes Vinay K. Gupta, Timothy B. Dubrovsky, and Rahul Shah, which are not listed in the instant application. The assignee of this patent is The Regents of the University of California, which is different from the instant application, Wisconsin Alumni Research Foundation.

Claim Rejections - 35 USC § 103

10. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

11. Claims 8-9 are rejected under 35 U.S.C. 103(a) as being obvious over Abbott et al. (US Patent 6,284,197 B1) in view of Leavitt et al. (US Patent 5,712,103).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter

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disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). For applications filed on or after November 29, 1999, this rejection might also be overcome by showing that the subject matter of the reference and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person. See MPEP § 706.02(l)(1) and § 706.02(l)(2).

The method of Abbott et al. is disclosed above.

Abbott et al. does not teach coating the substrate with bovine serum albumin.

Leavitt et al. teaches a method step where an assay involves an antigen or antibody (immunoglobulin) immobilized on a substrate and to minimize the non-specific binding by coating the substrate with bovine serum albumin (col. 10, line 2-12). Leavitt teaches that it is well known in the art that proteinaceous materials such as bovine serum albumin, are commonly used to coat solid substrate to reduce non-specific binding.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Abbott et al. by including a method step to minimize the non-specific binding by coating the substrate with bovine serum albumin as taught by Leavitt et al. Leavitt teaches that it is well known and advantageous to use bovine serum albumin to coat a solid substrate to reduce non-specific binding.

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12. Claims 10-13 and 15 are rejected under 35 U.S.C. 103(a) as being obvious over Abbott et al. (US Patent 6,284,197 B1).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention “by another”; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). For applications filed on or after November 29, 1999, this rejection might also be overcome by showing that the subject matter of the reference and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person. See MPEP § 706.02(l)(1) and § 706.02(l)(2).

The method of Abbott et al. is disclosed above.

Abbott et al. does not specifically teach the dimensions of the depressions (well). However, Abbott teaches that the size and complexity of the pattern on the substrate is limited only by the resolution of the technique utilized and the purpose for which the pattern is intended,

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which is to confine the analyte of interest (col. 17, line 7-27). Abbott teaches patterning the substrate such that features of about 1 μm - 200 nm are possible.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to vary the dimensions of the wells on the surface of substrate, as taught by Abbott, to meet the needs and to satisfy the purpose for which the pattern is intended, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

13. Claims 17-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Abbott et al. (US Patent 6,284,197 B1) in view of Leavitt et al. (US Patent 5,712,103) as applied to claims 8-9 above, and further in view of Chagnon et al. (US Patent 4,628,037).

The method of Abbott et al. as modified by Leavitt et al. is disclosed above.

Abbott et al. as modified by Leavitt et al. does not specifically include the use of magnetic beads.

Chagnon et al. teaches a binding assay method that involves using magnetic particles (beads) to measure the amount of analyte (col. 9, line 58-64). This method would permit a homogeneous reaction conditions that promote optimal binding kinetics and minimally alter analyte-adsorbent equilibrium (col. 2, line 51-55).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Abbott et al. as modified by Leavitt et al. by including a method step that involve using magnetic particles (beads) to measure the amount of analyte as

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taught by Chagnon et al. for the advantage of permitting a homogeneous reaction conditions that promote optimal binding kinetics and minimally alter analyte-adsorbent equilibrium.

Response to Arguments

14. Applicant's arguments filed 7/8/02 have been fully considered but they are not persuasive. Applicant contends that both Abbott et al. (US Patent 6,284,197 B1 and US Patent 6,277,489 B1) do not teach or suggest that their detection system is suitable for detecting a pathogen, specifically that the biomolecule is a pathogen. It is the examiner's position that both Abbott et al. patents do teach that their detection system is suitable for detecting a pathogen because in the presently claimed invention the binding agent use for detecting the pathogen comprising antibodies, peptides, or DNA (claim 14). In both Abbott et al., the recognition moiety (binding agent) use for detecting for detecting the biomolecule comprises antibodies, peptides, or nucleic acid (Abbott (6,284,197 B1): col. 29, lines 11-64; Abbott (6,277,489 B1): col. 19, lines 56-67 to col. 20, lines 1-26). Therefore, the detection system of both Abbott et al. can be use for detecting a pathogen. Further, a pathogen comprises of biomolecules for biomolecule is defined by both Encarta Dictionary and On-line Medical Dictionary (copies are enclosed with Office Action) as any molecules from which living organism are made. And a pathogen is defined as [a]ny microorganism which by direct interaction with another organism causes disease in that organism (definition provided by Applicant), therefore the term "biomolecule" would encompassed the term "pathogen". Therefore, the detection system used in the detection of biomolecules of both Abbott et al. patents anticipates the presently claimed invention.

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15. Applicant alleges that Abbott et al. (US Patent 6,284,197 B1) does not anticipate the presently claimed invention in regard with the rejection of Claims 1-7 and 14 under 35 USC 102(f). Abbott does anticipate the presently claimed invention as discussed above.

16. Applicant argue that Abbott et al. (US Patent 6,284,197 B1) in combination of with Leavitt et al. is not obvious because Abbott does not teach or suggest that their detection system is suitable for detecting a pathogen. It is the examiner position that Abbott in combination of with Leavitt is obvious because Abbott does anticipate the presently claimed invention as discussed above.

17. In regard to the rejection of claims 10-13 and 15, applicant contends that Abbott et al. (US Patent 6,284,197 B1) do not teach or suggest that their detection system is suitable for detecting a pathogen, specifically that the biomolecule is a pathogen. Thus, Abbott alone cannot teach or suggest the claimed depression sizes. It is the examiner position that Abbott can teach or suggest the claimed depression sizes because Abbott does anticipate the presently claimed invention as discussed above.

18. With regard to the rejection of Claims 17-18, applicant alleges the combination of Abbott et al. (US Patent 6,284,197 B1) combined with Leavitt et al. and further in view with Chagnon et al. is not obvious because Abbott does not teach or suggest that their detection system is suitable for detecting a pathogen. It is the examiner position that Abbott in combination of with Leavitt is obvious because Abbott does anticipate the presently claimed invention as discussed above.

Conclusion

19. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to My-Chau T. Tran whose telephone number is 703-305-6999. The examiner can normally be reached on M-F 7:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew J. Wang can be reached on 703-306-3217. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1123.

mct
October 16, 2002


ANDREW WANG
SUPERVISORY PATENT EXAMINER
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